ARC 3863C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to centralized prescription filling and processing

The Board of Pharmacy hereby amends Chapter 18, "Centralized Prescription Filling and Processing," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.301, 124.306, 124.308, 155A.13 and 155A.28.

Purpose and Summary

Pursuant to Iowa Code section 17A.7(2), the Board completed an overall review of this chapter of administrative rules. These amendments clarify records requirements, update language to be consistent with other Board rules, and remove redundancies that exist in other applicable chapters of Board rules. These amendments also remove the implication that central fill pharmacies can only enter into agreements with pharmacies that are in good standing.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on December 20, 2017, as **ARC 3512C**. The Board received two comments related to this rule making. One comment was in support of the Board's review of this chapter. The second comment did not provide specific concerns related to the amendments but rather provided suggested alternate language. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board on May 23, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's

meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on July 25, 2018.

The following rule-making actions are adopted:

ITEM 1. Amend rule 657—18.3(155A) as follows:

657—18.3(155A) General requirements.

18.3(1) *Essential qualifications.* An originating pharmacy may outsource prescription drug filling to a central fill pharmacy or prescription drug order processing to a central processing pharmacy provided the pharmacies:

a. Have the same owner or have entered into a written contract or agreement, which is available for inspection and copying by the board or its authorized agent, that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and

b. No change.

18.3(2) No change.

18.3(3) *Originating pharmacy responsibility.* Except as specifically provided by this subrule, the originating pharmacy shall be responsible for all dispensing functions as the term "dispense" is defined in rule 657—18.2(155A). An originating pharmacy contracting only for centralized filling shall retain responsibility for all processing functions, and an originating pharmacy contracting only for centralized processing shall retain responsibility for all filling functions.

a. No change.

b. A central fill or a central processing pharmacy that shares a common central processing unit with the originating pharmacy may perform prospective drug use review (DUR) pursuant to rule 657—8.21(155A). Only a pharmacist shall perform the DUR~~; the~~, and such review shall not be delegated ~~to a pharmacy technician, registered nurse, or other pharmacy support person~~. The pharmacist performing the DUR shall document in the shared patient record all concerns, recommendations, observations, and comments resulting from that review. The pharmacist at the originating pharmacy shall utilize the DUR notes in counseling the patient pursuant to rule 657—6.14(155A).

18.3(4) *Central fill label requirements.* The label affixed to the prescription container filled by a central fill pharmacy on behalf of an originating pharmacy shall include the following:

a. to *h.* No change.

i. The initials or other unique identification of the pharmacist ~~in the originating pharmacy~~ who performed drug use review ~~and transmitted the prescription drug order to the central fill pharmacy~~.

ITEM 2. Amend subrule 18.5(2) as follows:

18.5(2) *Exception.* The provisions of this rule do not apply to a patient in a facility, such as a hospital or ~~long-term~~ care facility, where Iowa law requires that drugs be administered to the patient by a health care professional.

ITEM 3. Amend rule 657—18.10(155A) as follows:

657—18.10(155A) Policy and procedures.

~~**18.10(1)** *Manual maintained.*~~ Pursuant to rule 657—8.3(155A), a policy and procedure manual relating to centralized filling or centralized processing activities shall be maintained at all pharmacies involved in centralized filling or centralized processing and shall be available for inspection and copying by the board or ~~an~~ its authorized agent ~~of the board~~.

~~**18.10(2)** *Manual contents.*~~ The manual shall:

~~*a.*~~ 1. Outline the responsibilities of each of the pharmacies;

~~*b.*~~ 2. Include a list of the names, addresses, telephone numbers, and all license and registration numbers of the pharmacies involved in centralized filling or centralized processing; and

~~*c.* Include evidence that all licenses and registrations have been verified to be current and in good standing, identifying the individual verifying license and registration status and the method used to verify status; and~~

~~*d.*~~ 3. Include, but not necessarily be limited to, policies and procedures for:

~~(1)~~ • Protecting the confidentiality and integrity of patient information;

~~(2)~~ • Protecting each patient's freedom of choice of pharmacy services;

~~(3)~~ • Maintaining appropriate records to identify the name, the initials or unique identification code, and the specific activities of each pharmacist or pharmacy technician who performed any centralized filling or centralized processing function; and

~~(4) Complying with federal and state laws, rules, and regulations;~~

~~(5)~~ • Operating a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems~~; and~~.

~~(6) Reviewing, at least annually, the written policies and procedures and documenting that review.~~

ITEM 4. Amend rule 657—18.15(155A) as follows:

657—18.15(155A) Records. Central fill or central processing pharmacies shall maintain appropriate records that identify, by prescription drug order, the ~~name and~~ initials or unique identification code of each pharmacist or pharmacy technician who performs a centralized filling or centralized processing function for a prescription drug order. Originating pharmacies shall maintain appropriate records that identify, by prescription drug order, the ~~name and~~ initials or unique identification code of the pharmacist who performed drug use review ~~and the pharmacist who transmitted the prescription drug order to the central fill or central processing pharmacy~~. These records may be maintained separately by each pharmacy or in a common electronic file as long as the data processing system is capable of producing a printout that lists the functions performed by each pharmacy and pharmacist or technician and identifies the pharmacist or technician who performed each function.

[Filed 5/29/18, effective 7/25/18]
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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/20/18.